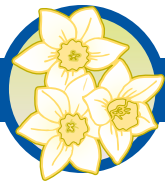


# HOT SPOT

The Newsletter of the Rapid Response Radiotherapy Program  
of the Odette Cancer Centre



Volume 14, Issue 2, May 2012

## Editorial

By Dr. Edward Chow

Time passes fast. We are already in May of 2012. Ms. Sally Bean discusses a timely problem—resource allocation during a drug shortage. Dr. Lisa Barbera outlines a population-based cohort research of elderly patients with cancer with regards to opioid prescrip-

tion after pain assessment. Dr. Mary Vachon writes on the mindful, compassionate professional. Dr. Marlene Jacobson describes, “What is a speech therapist doing in a cancer centre”. Dr. Arjun Sahgal provides new hope for patients with brain metastases using

stereotactic radiosurgery. Dr. Ewa Szumacher again outlines the CME activities. We have one insert this time, on quality of life assessment in lung cancer clinical trials.

We hope you find the newsletter useful.

## Ethics Resource allocation during a drug shortage

By Sally Bean, JD, MA

Drug shortages occur due to a variety of factors such as a manufacturer’s decision to reduce production, unavailability of material ingredients required to manufacture a particular drug or class of drugs, or unexpected increase in demand. The anticipated Canada-wide shortage of injectable drugs supplied by Sandoz is reportedly due to reduced manufacturing while Sandoz’s Boucherville, Quebec, plant is retrofitted to comply with Health Canada and the Food and Drug Administration Good Manufacturing Practices. The retrofitting process is expected to last between 12 and 18 months. A fire in March 2012 in the Quebec-based plant has also exacerbated the situation. The Ontario Hospital Association

has called on hospitals to activate their Incident Management Systems (IMS) to respond to the drug shortage that could impact patient care. IMS establish procedures for emergencies of relatively short duration. Specific plans for managing emergencies of indeterminate length, e.g., pandemic influenza, typically have unique topic-specific plans in place. Given that priority setting of scarce resources will occur during the current drug shortage, and drug shortages are likely to occur in the future, it is imperative that ethics is an essential component of any proposed solutions.

*continued on page 2...*

### In this issue of Hot Spot:

Ethics: Resource allocation during a drug shortage

What is a “speech therapist” doing in a cancer centre?

New hope for patients with a limited number of brain metastases

Opioid prescription after pain assessment: A population-based cohort of elderly patients with cancer

The mindful, compassionate professional  
Continuing Medical Education 2012–2013

#### Insert:

Quality of life assessment in lung cancer clinical trials

...continued from page 1

In light of the potential Canada-wide drug shortage, the overarching issue is that drug options for both patients and prescribers may be limited. Reduced drug options could negatively impact safe and effective health care delivery across the health care continuum. From an ethics perspective, the key question is how can we safely and fairly allocate scarce resources to patients across Canada, as well as within individual health care delivery institutions situated within the larger context? If/when decision-making limits on access to drugs are required, what will constitute a fair process?

There have been several studies demonstrating that the public endorses ethics-informed priority-setting.<sup>1</sup> While, under ideal circumstances, priority setting would be made well in advance of a crisis situation,<sup>2</sup> the short notice in the Sandoz drug shortage has undermined advance priority-setting. Nonetheless, a fair priority-setting process can still occur with an emphasis on incorporating key principles through expeditious action and constant revision, as additional information is obtained.

### Accountability for Reasonableness<sup>3</sup>

“Accountability for Reasonableness” (A4R) is an ethical framework that describes the conditions of a fair decision-making process. It focuses on *how* decisions should be made and *why* these decisions are ethical. There are five conditions that optimize fairness in the process of decision-making:

- **Relevance:** Decisions should be made on the basis of reasons (i.e., evidence, principles and values) that objective and reasonable people can agree are relevant to meeting diverse health needs under resource constraints.
- **Transparency:** Decisions and their rationales should be made publicly accessible and open to evaluation.
- **Revision:** There should be opportunities to revisit and revise decisions in light of further evidence or arguments.

- **Enforcement:** Institution/system has the ability to regulate the process to ensure that transparency, relevance and revision are upheld.
- **Empowerment:** There should be efforts to optimize the effective opportunities for participation in priority setting and to minimize power differences in the decision-making context.

In light of the A4R criteria, here are some initial recommendations to inform the current Sandoz drug shortage, as well as future considerations.

### I. Inventory management

1. Develop overarching principles that will guide the process for resource allocation decisions. Suggested principles include the following: equity, solidarity, trust, stewardship, proportionality and reciprocity. Adopted principles should be publicly available with the opportunity to provide feedback.
2. To facilitate fair and informed decision-making, inventory all affected (Sandoz-manufactured) drugs.
  - a. Develop a standardized inventory template that is completed by each institution. Ideally, the inventory is submitted to a higher-level governance body, e.g., Local Health Integration Network (LHIN) or Ministry body that can collate and coordinate inventory data.
  - b. Repeat drug inventories at designated time intervals, e.g., every 24 hours.
  - c. Establish thresholds for initiating modification of services when projected supply dips below a specified amount, e.g. less than five-day supply remaining AND the projected supply will not last until the next expected drug shipment.
  - d. In order to ensure equitable access in various health sectors, discourage hoarding of drugs.
3. Identify drugs for which there is no acceptable substitute (i.e., manufacturing cannot be done by another facility; no alternative drug substitute exists, etc.). Take into consider-

ation any potential contraindications (allergies, co-morbidities, etc.) for persons for whom the substitute may not be appropriate.

- a. All feasible avenues for obtaining a replacement or substitute should be pursued, e.g., international drug importation, provisional approval for drugs approved in other comparable jurisdictions (i.e., EU, United States), manufacturing by another company, etc.
  - b. Utilize resources such as drug information centres and expert-panels to help identify effective therapeutic drug alternatives.
4. Individual institutions project resource needs over anticipated drug shortage duration (in the case of Sandoz, up to 18 months) based on current activity levels.
  5. Collaborate with local institutions and governing bodies to facilitate resource sharing or redistribution where appropriate.

### II. Modification of health services

1. Enforce use limitations for drugs with an insufficient supply to maintain current activity levels or no drug replacement or alternative exists. This should be guided by the A4R framework and be a staged process that is proportional to the severity of the drug shortage. A potential staged approach to modification of services may include:
  - Conservation of drugs through use of therapeutic alternatives identified in the inventory management phase.
  - Cancellation of elective/non-urgent treatments or procedures that require administration of limited drug supply.
  - Prioritize patients based on severity of illness. Relevant factors may include: urgent nature of illness, degree of pain and suffering and ability to mitigate further health deterioration.
  - If patients of equal medical need require a drug and there is not enough for both, prioritize based on first-come, first-served.

continued...

# What is a “speech therapist” doing in a cancer centre?

By Marlene Carno Jacobson, PhD, SLP(C), Reg. CASLPO, Speech-Language Pathologist, Oncology Program

## III. Communication and monitoring

1. There should be ongoing and timely communication to health care stakeholders and the public of up-to-date information.
2. Follow institutionally established procedures for reporting adverse events related to the drug shortage and monitor so that processes can be revised as needed.

## Future recommendations

- Develop a clear definition of drug shortage with specified threshold(s) to trigger notification and, where necessary, priority-setting processes.
- Require mandatory pharmaceutical company notifications to Health Canada when a potential drug shortage is identified.
- Establish an acuity scale for future drug shortages with associated governance responsibilities depending on the scope and severity of the shortage. As a starting point, suggest mild, moderate, severe as the acuity classification scale that correlates with the expected duration and magnitude of harm.

Although it is best, where possible, to avoid modification of health care services, when difficult resource allocation decisions are required, an ethical framework developed through stakeholder engagement will help foster legitimacy and fairness in decision-making. Throughout the duration of the drug shortage and after it concludes evaluation of implemented processes should be assessed and refined. Decision-makers will be held accountable for *how* and *why* resource allocation decisions were made during the drug shortage.

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2. Ibid: 22.
3. Gibson J, Martin D, Singe P. Evidence, economics and ethics. *Healthcare Quarterly*. 2005;8(2).

Speech-language pathologists (S-LPs), in some countries known as “speech therapists,” play a relatively unfamiliar role to many in the contemporary outpatient oncology setting. Our profession is probably best known for its work with children and stroke patients.

Innumerable individuals working in health care and from other walks of life have posed this question to me. I usually explain that head and neck cancer in particular, a site of relatively uncommon malignancy, can prove to be an unfortunate location for “disruption”, since the anatomical structures at risk are mostly visible, and represent crucial “junctions” for the highest intricacies of uniquely human function, namely spoken communication (requiring cognition, language, voice and articulation) and swallowing of a diverse textural smorgasbord. To lose these capacities can shatter an individual’s quality of life. So many of life’s great pleasures are tied up with eating in company, expressing our views verbally, whether in quiet conversation or in large groups, and in living relationships with family and friends. These functions are not mere “frills”, although we take them entirely for granted. Eating and drinking are vital to having a healthy, well-hydrated body; speaking is essentially an oral passport to life, instrumental in earning a living, human connection, and self-advocacy.

S-LPs consult on cancer patients with malignancies of all oncologic disease sites but, most commonly, head and neck (larynx, pharynx, tongue, jaw), CNS/brain, breast, lung, and GI. Changes in orofacial, communicative and swallowing functions may arise as a result of either cancer itself, or the rapidly expanding array and combinations of treatment modalities, including surgical resection and reconstruction, radiotherapy, chemotherapy and biologic agents/ immunotherapies. A treatment goal of organ preservation does not always correspond with functional preservation.

The S-LP is a collaborator and patient-physician link within the interdisciplinary oncologic team, liaising with nursing,

allied health and physician colleagues throughout the management process, from diagnosis through the survival and/or palliation trajectories. We “translate” physical impact into functional terms, and advocate for our patients, seeking to maximize performance outcomes and, in turn, quality of life. Rehabilitative needs and challenges vary widely over the course of each individual’s illness, and require customized intervention.

In line with the trend in contemporary health care, we undertake a substantial portion of the “therapeutic process” with an eye on preventing impairment and educating on anticipated dysfunction. Thus, pre-treatment counselling, teaching and intervention related to the expected effects of treatment can avert angst, strengthen structures, prepare and empower patients with regard to their communicative and swallowing abilities. Whenever feasible, we attempt to get involved early rather than step in for the “rescue”. Our “tools” include the application of imaging techniques, such as videofluoroscopy and endoscopy, acoustic instrumentation, psychosocial skills and technical expertise in fitting prosthetic devices for voice production in laryngectomized individuals. We work through acute changes in functional status, as well as the late onset of treatment sequelae arising years later. Our intervention strategies seek to ameliorate and compensate for impairment. Ultimately, we strive to minimize the broader functional impact of cancer treatment on individuals and their loved ones.

## About the author

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# New hope for patients with a limited number of brain metastases

By Arjun Sahgal, MD, FRCPC

Sunnybrook oncologists are giving new hope to individuals living with brain cancer. Using a highly targeted high-dose radiation treatment called stereotactic radiosurgery, Dr. Arjun Sahgal and colleagues at Sunnybrook's Odette Cancer Centre are extending the quality of life for patients with brain metastases, and helping them hold onto more of the brain's neurocognitive function. Stereotactic radiosurgery is a high-precision radiotherapy technique that allows the delivery of high doses of radiation to a focused tumour location in the brain, while significantly sparing healthy brain tissue that supports thought processes such as attention span, memory, problem-solving, decision-making and language skills.

"The management of brain metastases is more complex with emerging radiation technologies. In the past we simply blanketed the whole brain with radiation in the hopes to palliate patients. We now deliver focal high-dose radiation to control the tumours for patients who present with a limited number of metastases (typically up to four) and save the whole brain radiation for later, if and when they need it. The aim is to preserve the patient's memory functioning, avoid delays in chemotherapy and improve the patient's tolerability to chemotherapy given that the side effects of whole brain radiation can leave people feeling very tired," says Dr. Arjun Sahgal, Radiation Oncologist at Sunnybrook's Odette Cancer Centre, and an international research leader in brain and spine cancers. "Beyond radiation we also have a targeted MRI guided brain ultrasound device that we are starting to use for patients with prior radiation who need focal therapy," says Sahgal, also an assistant professor of radiation oncology and surgery in the Department of Radiation Oncology at the University of Toronto.

As testament to his leading work in this area, he and radiation oncology colleague, Dr. May Tsao of the Central Nervous System Cancer Care Group at the Odette, were recently

honoured by the European Association of Neuro-Oncology. Their publication, *A Meta-Analysis Evaluating Stereotactic Radiotherapy, Whole Brain Radiotherapy or Both for Patients Presenting with a Limited Number of Brain Metastases* was recognized as one of the best neuro-oncology articles of 2011 among a select group of papers by researchers from around the world published in journals including *Lancet Oncology*, *Cancer*, *Journal of Clinical Oncology*, *Science*, *Cell*, and *New England Journal of Medicine*. Stereotactic radiosurgery does not remove the tumour, but disables the DNA or genetic instructions within the tumour cells. The cells then lose the ability to reproduce and hold fluids, which leads to tumour reduction or

control. Because of the high-precision aspect of this therapy, expertise and collaboration are vital to effective treatment, and the radiation oncologists work closely with their neurosurgeon colleagues.

Sunnybrook's Odette Cancer Centre is one of only a few centres in Canada providing stereotactic radiosurgery for brain and spine metastases, and related stereotactic body radiotherapy for the treatment of lung and liver tumours. At the centre, radiation oncologists work closely with medical physicists who engineer precise equipment functionality, dosimetrists who carefully plan dose delivery, and radiation therapists who meticulously deliver the therapy to the patient. For referral, please contact Dr. Sahgal at 416-480-4244.

## Opioid prescription after pain assessment: A population-based cohort of elderly patients with cancer

By Lisa Barbera, BSc, MD, MPA, FRCPC

The purpose of this study was to measure opioid prescription (OP) rates in elderly cancer outpatients around the time of assessment for pain, and to evaluate factors associated with receiving OPs for those with severe pain. The cross-sectional cohort used in the study includes all patients with cancer in Ontario older than age 65 years who completed a pain assessment as part of a provincial initiative of systematic symptom screening. Patients were assigned to mutually exclusive categories by pain score severity: 0, 1 to 3 (mild), 4 to 6 (moderate), and 7 to 10 (severe). We linked multiple provincial health databases to examine the proportion of patients with an OP within seven days after or 30 days before the assessment date. We examined factors associated with OPs for patients with pain scores of 7 to 10.

The proportion of patients with an OP increased as pain score severity increased: 10% of those with no pain, 24% of those with mild pain, 45% of

those with moderate pain, and 67% of those with severe pain. More specifically, for those with severe pain, 41% filled an OP within seven days of assessment for pain, and 26% had an OP from the 30 days before assessment for pain, leaving 33% without an OP. In multivariable analysis, factors associated with OPs are younger age, male sex, comorbid illness, cancer type and assessment at home.

Despite a generous time window for capturing OPs, the proportion of patients without an OP seems high. Further knowledge translation is required to maximize the impact of the symptom screening initiative in Ontario and to optimize management of cancer-related pain.

*Barbera, L., et al. Opioid prescription after pain assessment: A population-based cohort of elderly patients with cancer. J. Clin Oncol., 2012, 30(10), 1095-1099. Reprinted with permission. ©2012. American Society of Clinical Oncology. All rights reserved.*

# The mindful, compassionate professional

Mary Vachon, PhD, RN

As professionals, we are called to serve the patients referred to us. Dr. Rachel Naomi Remen<sup>1(p197)</sup> writes, “Basically service is about taking life personally, letting the lives that touch yours touch you”. She contends that service is a relationship between equals. When you serve, the work itself keeps you from burnout.

In *Mindful Leadership: The 9 Ways to Self-Awareness, Transforming Yourself, and Inspiring Others*, Maria Gonzalez, a Toronto mindfulness meditation teacher, speaks of service and notes that the role of a leader is to be of service. Gonzalez defines a leader as anyone who is in a position to influence others, so health care professionals are, by the nature of our work, leaders who serve.<sup>2</sup>

Gonzalez says that the mindful leader has nine characteristics. S/he is: present, aware, calm, focused, clear, equanimous, positive, compassionate and impeccable. A Buddhist definition of compassion is ‘wanting others to be free from suffering. To generate genuine compassion, one needs to realize that one’s self is suffering, that an end to suffering is possible, and that other beings similarly want to be free from suffering.’<sup>3</sup>

In order to be compassionate to others, however, we must first develop self-compassion, an attribute not always easy for health care professionals. Mindfulness meditation and other self-care activities can help us to develop the self-compassion that is essential for true compassion. Mindfulness meditation brings into awareness one’s own physical being, thoughts, feelings and sensations. Recent neuroscience research shows that the ability to tune into one’s own body sensations activates the same brain circuits (within the insula cortex) as those of empathy.<sup>4</sup> Halifax suggests

this may be one base for the development of empathy and compassion.<sup>5</sup> So, self-awareness and self-compassion may prime our brains towards empathy and compassion for others. Medical residents who were sufficiently attentional to their own needs to engage in self-care activities were able to care for their patients in a sustainable way with greater compassion, sensitivity, effectiveness, and empathy.<sup>6</sup>

“Leaders who are compassionate have deep caring without attachment. They do their best each and every moment of the day, under the circumstances. They understand the importance and value of self-compassion, because they know that without taking care of themselves, their ability to serve and to perform at a high level is not sustainable.”<sup>2(p7)</sup>

True compassion is deep caring without attachment. This is not the same as deep caring with detachment, which would imply an arm’s-length relationship that does not touch you, where you could not feel the pain or get hurt in the process of caring.”<sup>2(p164)</sup> This compassion is caring deeply, but not being attached to the outcome. True compassion with non-attachment to outcome builds resilience and keeps us from burning out. Attachment refers to the unrelenting drive to succeed, to acquire, to compete, to control, and to the inability to let go.<sup>2(p64)</sup>

How can caring professionals not be attached to what happens as a result of our hard work? Gonzalez notes that attachment is a “hindrance.” Hindrances are mental states that get in the way of your “realizing your full potential as a leader and experiencing personal fulfillment, and they cause great suffering.”<sup>2(p63)</sup>

As professionals, we often care deeply about our patients. These rela-

tionships are a primary source of the satisfaction that serves to keep us going in our work. According to Gonzalez, you can care deeply about a person or situation, but you are not attached to the outcome of your intervention or the outcome of what occurs. “That is true compassion. There is real wisdom in this. And you always want the appropriate blend of wisdom and compassion. Not enough wisdom and you risk being a bleeding heart. Not enough compassion and you risk being cruel.”<sup>2(p165)</sup>

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# Continuing Medical Education 2012–2013

By Ewa Szumacher, MD, FRCP(C)

Continuing Medical Education (CME) can update health care professionals on the latest advances for modifications to their clinical practice. At the request of the CME organizers, Hot Spot will list the national and international CME activities in palliative medicine that are of interest to our readers. Please forward details of the CME activities to: [Ewa.Szumacher@sunnybrook.ca](mailto:Ewa.Szumacher@sunnybrook.ca)

- **June 1–5, 2012**  
2012 American Society of Clinical Oncology (ASCO) Annual Meeting  
[www.eurolink-tours.co.uk/Oncology\\_congress/2012-asco-annual-meeting-1-860.html](http://www.eurolink-tours.co.uk/Oncology_congress/2012-asco-annual-meeting-1-860.html)
- **June 4–6, 2012**  
International Death, Grief and Bereavement Conference: Hospice and Palliative Care  
[www.uwlax.edu/conted/dgb/](http://www.uwlax.edu/conted/dgb/)
- **June 7–9, 2012**  
8th Annual Advanced Learning in Palliative Medicine Conference  
[www.ubccpd.ca/Events/CPD\\_Conferences/8th\\_Annual\\_Advanced\\_Learning\\_in\\_Palliative\\_Medicine\\_Conference.htm](http://www.ubccpd.ca/Events/CPD_Conferences/8th_Annual_Advanced_Learning_in_Palliative_Medicine_Conference.htm)
- **June 10–12, 2012**  
International Conference on Opioids (ICOO)  
[www.pnpco.com/13098.pdf](http://www.pnpco.com/13098.pdf)
- **June 14–17, 2012**  
World Conference on Interventional Oncology  
[www.wcio2012.org/p/cm/ld/fid=1](http://www.wcio2012.org/p/cm/ld/fid=1)
- **June 28–30, 2012**  
MASCC/ISOO 2012 – The Cancer Care Symposium  
[www2.kenes.com/mascc/pages/home.aspx](http://www2.kenes.com/mascc/pages/home.aspx)
- **July 5–6, 2012**  
British Gynaecological Cancer Society Annual Scientific Meeting  
<http://bgcsconference.com/>
- **July 14–15, 2012**  
Singapore Palliative Care Conference 2012  
[www.spconference.org](http://www.spconference.org)
- **August 27–30, 2012**  
World Cancer Congress  
[www.worldcancercongress.org](http://www.worldcancercongress.org)
- **September 13–15, 2012**  
Breast Cancer Symposium  
<http://breastcancersymposium.org>
- **October 9–12, 2012**  
19th International Congress on Palliative Care  
[www.palliativecare.ca/en/](http://www.palliativecare.ca/en/)
- **October 28–31, 2012**  
ASTRO's 54th Annual Meeting  
[www.astro.org/Meetings/AnnualMeetings/index.aspx](http://www.astro.org/Meetings/AnnualMeetings/index.aspx)
- **November 22–25, 2012**  
The 2nd International Multidisciplinary Forum on Palliative Care  
[www.imfpc.org](http://www.imfpc.org)
- **December 4–8, 2012**  
CTRC-AACR San Antonio Breast Cancer Symposium  
[www.sabcs.org](http://www.sabcs.org)
- **February 14–16, 2013**  
2013 Genitourinary Cancers Symposium  
[www.gucasym.org](http://www.gucasym.org)
- **March 13–16, 2013**  
13th St. Gallen International Breast Cancer Conference 2013  
[www.oncoconferences.ch](http://www.oncoconferences.ch)
- **March 20–22, 2013**  
2013 17th Reach to Recovery International Conference  
[www.reachtotherecovery2013.org](http://www.reachtotherecovery2013.org)

The newsletter of the Rapid Response Radiotherapy Program of the Odette Cancer Centre is published through the support of:

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## Vol. 14, Issue 2, May 2012

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Produced by Pappin Communications,  
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